

IN THE UNITED STATES PATENT
AND
TRADEMARK OFFICE

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APPLICATION OF

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FOR

UNITED STATES LETTERS PATENT

ON

MULTIFUNCTION CATHETER

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MULTIFUNCTION CATHETER

This invention pertains to a medical catheter for insertion into the human body. More particularly, the catheter is adapted for, but not limited to, insertion along the urethra into the bladder to measure various vital signs as well as to drain the bladder.

BACKGROUND OF THE INVENTION

In trauma and many operative cases it is customary to insert a catheter into the bladder very early on to drain the bladder, detect some forms of internal damage, and monitor urinary output, and potentially provides passage for insertion of other instruments. Temperature measurements can be readily made by way of the catheter duct with electronic sensors now available. Internal pressure, intra-abdominal, may need to be monitored in many cases and here also electronic related sensors provide means to monitor pressure by way of the catheter access. The mucosa lining the genito-urinary and gastro-intestinal tracts has vascular features that facilitate blood oxygen level determinations. The usual practice involves the use of a light source and a light sensitive sensor, attached to available body areas, that indicates oxygen level in the blood by it's light response characteristics. Externally applied, these systems sometimes become dislodged. Modern light sources and sensors suggest the use of the catheter structure as convenient access for oximeter functions. The vessels of the mucosa pulse with the heartbeat and provide a convenient pulse rate detector with readily available adaptation of the electronic signal processor activity related to the blood oxygen sensor.

The development of miniature sensors and closely related signal carriers invited and was attended by an increase in the number of data gathering functions considered necessary. The apparatus grew smaller but the number increased. The work area became cluttered. Connections of monitoring devices to external instrumentation became more tedious and invited errors. The loss of monitor information at critical points was, and is, dangerous.

There is a need to combine a number of medical data gathering intrusive devices into the envelope of one of those devices deemed necessary so that the effect of only one intrusion is borne by the patient and patient care area. Further, when time is assumed to be vital, the use of a single catheter, capable of a plurality of functions, is of value in terms of time economy and certainty of correct connections. In addition, the security of device placement and the acquisition of reliable data, being critical, is significantly advanced by the combination of these modalities.

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2 It is therefore an object of this invention to provide via the catheter apparatus a
3 combination of data gathering functions in one catheter envelope.

4 It is yet another object of this invention to provide a urethral catheter with a built in
5 temperature measuring capability, a built in pressure measuring capability, a built in blood
6 oxygen measuring capability and a built in pulse rate measuring ability, with a balloon near
7 the insertion end of the catheter for anchoring the assembly within the urinary bladder, thus
8 assuring the correct and stable placement of the various monitoring devices.

9 These and other objects, advantages, and features of this invention will be apparent to
10 those skilled in the art from a consideration of this specification, including the attached claims
11 and appended drawings.

12 13 SUMMARY OF THE INVENTION

14 A modified Foley catheter has fluid conduits molded into the tube wall material to
15 provide a passage to inflate a balloon near the insertion end for anchoring the catheter in the
16 body. Wire conductors, and fiber optics elements if used, imbedded in the catheter structure
17 provide power and sensor related circuits for a light near the insertion end, a temperature
18 sensor, a pressure sensor and a blood oxygen level sensor. The associated external
19 instrumentation, not part of this disclosure, provides power control and interpreter functions
20 for the light, the pressure sensor, and the temperature sensor. The oxygen sensor reacts to the
21 light characteristics as modified by vascular content between the light source and the sensor
22 and, in conjunction with associated external signal processing means, alluded to above,
23 processes the signal to provide an indication of the level of oxygen in the blood. The
24 instrumentation related to the oxygen sensing action can, within the realm of current art,
25 responds to the pulsation of light received by that sensor and provide signal conditioning
26 ability to indicate pulse rate. No additional conductors and sensors are needed for the pulse
27 sensing function. The light source and oximeter sensor emit and receive through a thin
28 portion of the catheter wall. The catheter, in general, follows the well known Foley
29 configuration.

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2 BRIEF DESCRIPTION OF DRAWINGS

3 In the drawings wherein like features have similar captions, figure 1 is a side view of
4 the novel catheter.

5 Figure 2 is a fragmentary side view, somewhat enlarged, and partially cut away, of the
6 insertion end of the novel catheter.

7 Figure 3 is a side view, similar in scale of that of figure 2 but showing an area farther
8 yet from the insertion end.

9 Figure 4 is a side view, similar in scale to that of figure 2 but showing a region farther
10 from the insertion end in the region captioned as 3 in figure 1.

11 Figure 5 is an orthogonal view of the view of figure 4.
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13 DETAILED DESCRIPTION OF DRAWINGS

14 In the drawings certain features well established in the art and not bearing upon points
15 of novelty are omitted in the interest of descriptive clarity. Such omitted features may include
16 layered structure of the general embodiment.

17 In figure 1, tubular body 1 is terminated by funnel opening end 4b at the access end
18 and tapered insertion end 2. The usual generally central catheter conduit 4 extends from the
19 common opening 4b at the access end to the dual openings 4a near the tip of the insertion
20 end. The retention balloon 5 is shown inflated by dashed lines. Intrinsic light sources and
21 sensors distributed along length 3, yet to be described, depend upon the usual external
22 control and signal processing means to be connected by the multi-conductor connector 8
23 pending from neck 7. Preferably, all imbedded conductors terminate in one connector.
24 External circuitry demands may dictate separate connectors for different groups of
25 conductors in which case more than one connector, pending from related necks, will be used.
26 The balloon requires a fluid conduit, described later, and that conduit terminates in opening
27 5b in nipple 10 pending from neck 9.

28 In figure 2, the insertion end is enlarged and passage end 4 is shown to open from the
29 sides 4a of the point 2. Element 13 is a pressure sensor of a miniature type that is commonly
30 available and is imbedded, or molded, into the wall of the end portion of the catheter. Wires
31 14, probably two, are imbedded in the catheter general structure.

32 Figure 3 relates to a balloon arrangement that is used to anchor the catheter within
33 the body. Annular plenum, or peripheral chamber, 5a, with a thin membrane outer shroud 5c,
34 is intrinsic to the catheter tube, sometimes attached as a membrane sleeve, surrounds the
35 catheter body and is fluidly connected with channel 5b by which the annular space can be

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1 expanded by inflation to provide a bulge 5 on the catheter to anchor it in the body. This
2 balloon structure is common to the well known Foley catheter. Dashed lines illustrate the
3 expansion nature of the balloon feature.

4 Figure 4 shows the light emitting device, fiber optic or diode, 3a molded into the
5 catheter wall and arranged to emit light outward through a covering compatible with the
6 catheter purpose. The light sensitive sensor 3b, also molded into the catheter wall, is arranged
7 to receive light, fluorescently responsive to or reflected from the surrounding tissue in
8 response to light projected from source 3a. The sensor is selected and arranged to produce an
9 electrical output characteristic that is related to the blood oxygen concentration in the
10 illuminated tissue. The sensor is dependent upon external signal processor means to be
11 accessed by conductors imbedded, or molded into, the catheter wall and those conductors are
12 captioned as a group 3e emerging from the cutaway catheter. Conductors shown are
13 symbolic and may involve several individual conductors as required by the particular
14 contrivances specified. When associated with external signal processor means, the sensor, as
15 a pulse and oximeter component, is old art and currently available.

16 Figure 5 is an orthogonal projection of figure 4. Temperature sensor 3c, not visible in
17 figure 4, is imbedded in the catheter wall and has an associated conductor means 3d, also
18 embedded. Arrows P and R represent light paths permitted by the catheter outer material.
19 The conductor means may include a ground line common to all electrical contrivances in the
20 catheter, all of which will eventually lead to the connector 8. The temperature sensor is old
21 art, when associated with external signal processor means.

22 Well established in the instrumentation art the light source and sensors defined herein
23 and accessible by way of connector 8 will be supplied with a specification known as "pin
24 outs" that relate the characteristics of the imbedded electrical contrivances. From the "pin
25 out" specifications, instrument specialists define the related external signal conditioner and
26 indicator, including recorder, systems that empower the catheter user to utilize the catheter
27 system for the intended purpose. Every sensor intrinsic to the novel catheter is now in use in
28 the medical community in one form or another and the total functions defined herein can be
29 achieved by a plurality of available devices. In the realm of patient management related
30 activities, the plurality is a problem in that an assembly of individual systems take time, space,
31 attention to detail, and generally clutter up a busy environment where time saved, certainty of
32 function, and simplicity of installation can save lives.

33 It will be understood that certain features and sub-combinations are of utility and may
34 be employed without reference to other features and sub-combinations. This is contemplated
35 by and is within the scope of the claims.

1 As many possible embodiments may be made of the catheter of this invention without
2 departing from the scope thereof, it is to be understood that all matter herein set forth or
3 shown in the accompanying drawings is to be interpreted as illustrative and not in a limiting
4 sense.

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